Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

12975

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April 30, 1998

Food and drug administration
5600 Fishers Lane
Rockville, MD. 208 57

Attention consumer relations department,

Enclosed are letters I have written to [redacted] and Twin Labs. Inc. I would like you to send me any information you have on this Diet Fuel that is on the market and I'm sure the many health repercussions I' sure they have caused . I hope and pray you fine administration is working to get these dangerous and terrible products off the market. Please keep me informed.

Twin Laboratory has in the past been a great vitamin company, as you can tell by my wording I no longer feel that way . My son [redacted] thought as I did anything you would purchase from Twin Laboratory would not harm you or damage your health. You company has a product purchased at [redacted] called DIET FUEL and many diet products like that. This particular product has MU HUNG in which is just like amphetamine [redacted] has always been a healthy person, NEVER had any seizures before. I KNOW THE DIET FUEL he had been taking for a year was the reason he had a seizure on Jan. 2, 1998 . He was in the hospital three days, had a battery of tests and is on dilantin to this day. There have been over 800 seizures reported, not to mention strokes, heart attacks and any others health side affects. I cannot tell you how distressed I am that your company continues to sell these products in good conscience knowing these products are so detrimental to the publics health. This product is banned in many states so why is it not banned in [redacted] on your good name. I am also contacting [redacted] who are just at fault. I await your reply!

[redacted]

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98-B200

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For VOLUNTARY reporting by health professionals of adverse events and product problems

Page ____ of ____

Form Approved: OMB No. 0910-0291 Expires:12/31/94
See OMB statement on reverse

FDA Use Only

Triage unit sequence #

ARMS # 12975

A. Patient information

1. Patient identifier	2. Age at time of event: or Date of birth:	3. Sex	4. Weight
[redacted] In confidence	23	☐ female ☒ male	____ lbs or ____ kgs

B. Adverse event or product problem

1. ☒ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

- ☐ death ______ (mo/day/yr)
- ☐ life-threatening
- ☐ hospitalization – initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ other: ______

3. Date of event (mo/day/yr): 1/2/98

4. Date of this report (mo/day/yr): 3/3/99

5. Describe event or problem

Pt. began taking Diet Fuel ≈ 2/1/97. He states that he took it according to directions: 1 in AM, 1 before workout & 1 after workout. Eventually he increased the dose to 3 in AM, 3 before workout & 3 after workout (he estimates ≈ 3hrs. between the 2 workout doses). On 1/2/98 he had a seizure while at home. His parents heard him during the seizure & called paramedics. Estimated that the seizure lasted ≈ 10 minutes. Taken to ER & admitted for W/U & treatment. Begun on Dilantin. Current dose is 500 mg / day. No further episodes.

Pt. reports that prior to episode on 1/2/98, he had episodes of "staring off" and "lost in space," each

6. Relevant tests/laboratory data, including dates

lasting 15-20 sec. Had as many as 30 of these episodes.

No family history of seizures other than mat. grandfather who developed seizures 2° to MVA. Pt. well otherwise.

EEG at hospital: "mildly abnormal". Repeat

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

EEG not obtained.

Followed by a neurologist - Dr. [redacted] (? sp)

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C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 Diet Fuel - purchased at [redacted]. Consumer no longer has product

#2 → ingredients: mahuang, caffeine

2. Dose, frequency & route used

#1 See description -

#2 Started with 1, 3x/day

3. Therapy dates (if unknown, give duration) from/to (or best estimate)

#1 ≈ 2/97 - 1/98

#2

4. Diagnosis for use (indication)

#1 Increase metabolism for

#2 workout

5. Event abated after use stopped or dose reduced

#1 ☐ yes ☐ no ☐ doesn't apply

#2 ☐ yes ☐ no ☐ doesn't apply

6. Lot # (if known)

#1

#2

7. Exp. date (if known)

#1

#2

8. Event reappeared after reintroduction

#1 ☐ yes ☐ no ☐ doesn't apply

#2 ☐ yes ☐ no ☐ doesn't apply

9. NDC # (for product problems only)

10. Concomitant medical products and therapy dates (exclude treatment of event)

None

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device

- ☐ health professional
- ☐ lay user/patient
- ☐ other:

5. Expiration date (mo/day/yr)

6. model # ______

catalog # ______

serial # ______

lot # ______

other #

7. If implanted, give date (mo/day/yr)

8. If explanted, give date (mo/day/yr)

9. Device available for evaluation? (Do not send to FDA)

☐ yes ☐ no ☐ returned to manufacturer on ______ (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

* Taken by telephone by: N. Slifman, M.D. Medical Officer/CRRS

E. Reporter (see confidentiality section on back)

1. Name, address & phone #

[redacted]

2. Health professional? ☐ yes ☑ no

3. Occupation

4. Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an " X " in this box. ☐

FDA

Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to:
1-800-FDA-0178

FDA Form 3500 (6/93)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

MEMO TO THE FILE

June 25, 1999

Re: ARMS # 12975

By: Nancy Slifman, M.D. NS.
Medical Officer

I spoke with the mother of the patient today (the patient was away at college) to clarify the onset of the patient's "staring spells." She stated that the patient's "staring spells" began <u>after</u> he had begun to use Diet Fuel.